(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: 0 203 310 A2

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 86104276.0

(22) Date of filing: 27.03.86

(51) Int. Cl.4: A61H 23/04 , A61H 31/00

The title of the invention has been amended (Guidelines for Examination in the EPO, A-III, 7.3).

(30) Priority: 01.04.85 CN 85200905
23.12.85 CN 85109285
03.03.86 CN 86101234

(43) Date of publication of application: 03.12.86 Bulletin 86/49

(84) Designated Contracting States: CH DE GB IT LI SE

(71) Applicant: Biomedical Engineering Development Center of Sun Yat-sen University of Medical Sciences
No. 74, Zhongshan Rd.
Guangzhou(CN)

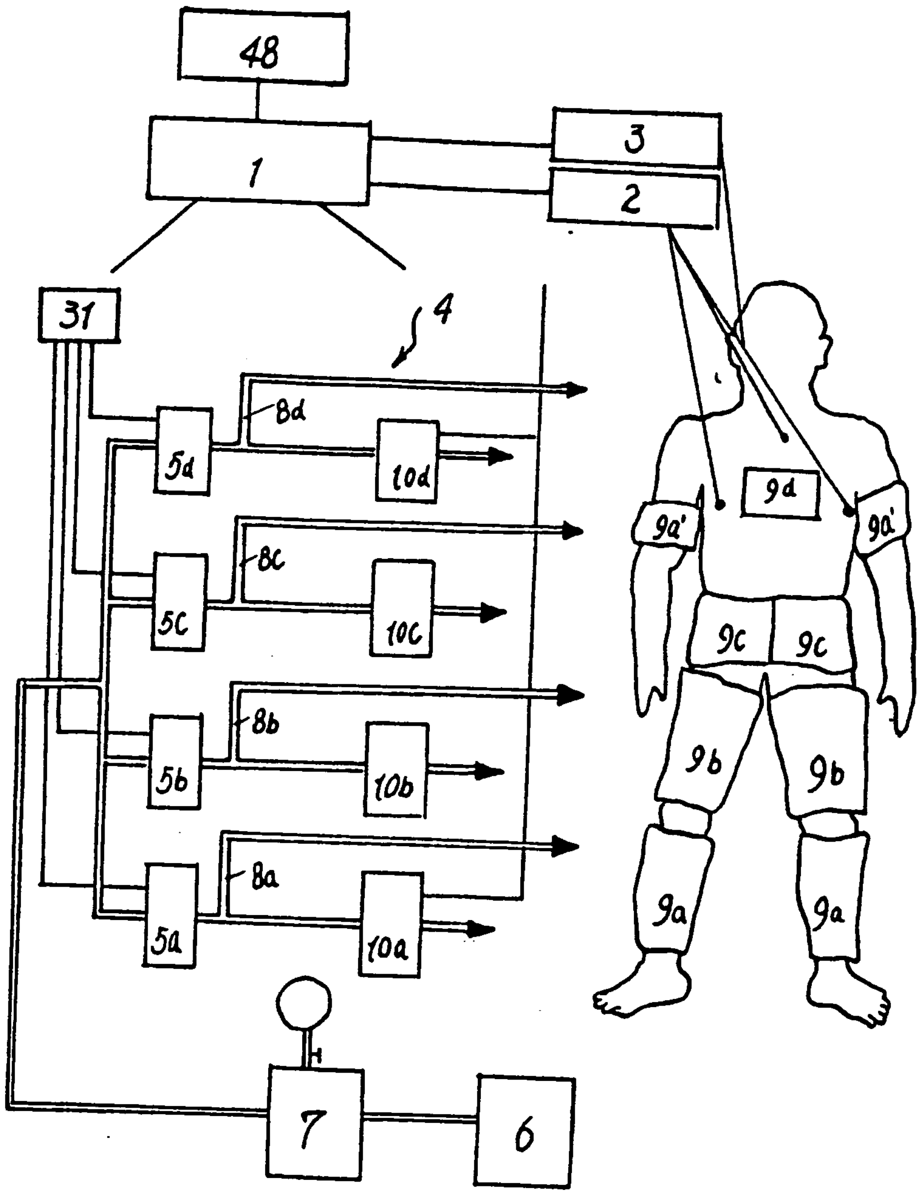
(72) Inventor: Zhensheng, Zheng
Apr. 701 No. 22, Zhushi Village
Zhixin Rd. Shouth Guangzhou(CN)
Inventor: Yutian, Wu
Apt. 204 No. 65
Zhixin Rd. Shouth Guangzhou(CN)

(74) Representative: Ebbinghaus, Dieter et al
v. FÜNER, EBBINGHAUS, FINCK
Patentanwälte European Patent Attorneys
Mariahilfplatz 2 & 3
D-8000 München 90(DE)

(54) Apparatus combining external counterpulsation massage and external cardiac massage.

(57) A combinated device is provided for a microcomputerized and enhanced type of external counterpulsation and extrathoracic cardiac massage apparatus. In addition to balloons for the 4 limbs, the device comprises a pair of lower-abdomen-buttock ballons and a chest balloon. It is controlled by microcomputer process. The various sets of balloons are sequentially inflated from the distal portion to the proximal portion during the diastolic period of the heart beat. The pressure is applied from the distal to the proximal portion gradually onto the 4 limbs, lower abdomen buttock and lower portion of the sternm.At the beginning of the cardiac systole all of the balloon deflate simultaneously. The cycle is then repeated. This device is used for the treatment of diseases of the heart, the brain, the kidneys, the ischemic disease of the retina and the peripheral vascular disease with apparent curative effect. For those cases of sudden cardiac arrest, the computer gives orders according to need, so that the abovementioned sets of balloons exert pressure sequentially from the distal portion to the proximal portion to force the blood to the abdomen, the chest and the head. Thereafter the device deflates suddenly, and then again the balloons sequentially inflate from the proximal portion to the distal portion to force blood back to the lower portion of the body. Thus the circulation goes on wavelike in succession to support adequate output as well as adequate cardiac blood inflow, and improves the effect of resuscitation.

0 203 310


48
1
3
2
31
4
8d
5d
10d
8c
5c
10c
8b
5b
10b
8a
5a
10a
7
6
9d
9a'
9a'
9c
9c
9b
9b
9a
9a

A Combined Device For a Computerized and Enhanced External Counterpulsation and extra-thoracic Cardiac Massage Apparatus

The present invention relates to a new instrument for physical treatment. Virtually, it provides a new type of combination for a computerized and enhanced model of external counterpulsation and extrathoracic massage apparatus.

In the American Cardiavascular Journal (32 (10) 656 -661. 1973) Dr. Cohen has reported a device for external counterpulsation, a four-limb sequential counterpulsation device. It consists of multiple balloons wrapped around the four limbs of the patient. The pressure is applied sequentially from the distal portion to the proximal portion of the four limbs. Using high pressure gas for its source of energy (1000-1750 mm Hg) and by controling the time of opening of the solenoid valve, the balloons receive a fixed amount of air during inflation; and by using a vacuum pump the balloons deflate. The necessity of using a large air-compressor vacuum pump set and pressure monitoring device insures that no excessive pressure is exerted in the ballons. However this bulky device causes loud noise in this complicated operation, and at high cost, so that it is not suitable for clinical use.

The inventor of the above mentioned device, however has introduced and adopted another device of sequential counterpulsation on the four limbs without the source energy from high-pressure gas and the vacuum pump. The device makes use of a low-pressure large-flow pump to supply oil-free gas. In this way the size of the apparatus is decreased and the noise is reduced to below 62 dB. Owing to the adoption of a larger channel and fixed time of inflation (100 ms) and keeping the pressure in the gas reservoir at 270-300mmHg, the pressure in the balloons is constant. There is no need to install a pressure monitoring system, and so the operation is relatively simple. The diastolic pressure is augmented by 32%. Ear-pulse-wave has shown that the ratio of diastolic wave amplitude to that of systolic wave amplitude (D/S) is equal to 1.32 ± 0.19. The clinical and experimental data have shown that in order to get better counterpulsation effect and to promote the establishment of collateral circulation it is necessary to raise the diastolic pressure to a certain level.

In that device of counterpulsation the augmentation of diastolic pressure is not conspicuously enough. Besides, the ECG analogue filter, the R wave detector and the R-R integrator of the inflation-deflation processing device are all part of the analogue circuit. Therefore, the control of inflation-deflation timing is less accurate and their range is small. The device has no automatic delay control function, occupying more space and emitting a loud noise. The bed for counterpulsation is flat and therefore uncomfortable for the patient. The clinical results are not satisfactory

Besides, the extrathoracic cardiac massage apparatus in current use is one that is placed at the lower portion of the sternum. The massage head is periodically lowered down and presses over the sternum so that pressure is exerted over the heart and the great vessel underneath, thus drives the blood to the periphery to achieve resuscitation. Yet this method cannot expel an adequate amount of blood from the heart and the big vessels in the left chest. The amount of blood expelled is limited and cannot meet the physiological requirements. When the chest receives pressure the venous blood is expelled from the chest cavity. Due to the relaxation of the peripherical vessels, a great amount of blood is stored in the blood vessels, which in turn causes brain anoxia. Besides, the brain anoxia and the relaxation of the peripheral vessels, a great amount of blood is stored in the blood vessels so that the return of venous blood to the heart is decressed, central venous pressure is low , cardiac output diminishes, the arterial perfusion to the brain is low and is even lower to the cardiac muscles. Through years of clinical practice this method has proved that it offers less chance of resuscitation.

Accordingly, it is a primary object of the present invention to provide a combinated device for an external counterpulsation and extrathoracic cardiac massage apparatus. Its purpose is to augment the diastolic pressure of the aorta and cardiac output , to improve anoxemia and thus to effect the counterpulsation and resuscitation more efficiently.

Another object of the present invention is to provide a control system of the combinated device for external counterpulsation and extrathoracic cardiac massage, which has the ability to select the proper time of inflation and deflation in relation to the exact time of the pulsation. This will improve precision of control of the timing of inflation and deflation.

Still another object of the present invention is to provide a combinated device of external counterpulsation and extrathoracic cardiac massage, the volume of which is small, with well muffled noise, and easy operation for clinical use.

A further object of the present invention is to provide a special bed for treatment with the combinated device for external counter-pulsation and extrathoracic massage. This bed gives the patient a comfort and proper placement of the massage apparatus, and thus achieves a better result of the treatment.

Additional objects, advantages, and other novel features of the invention will be set forth in part in the description that follows and in part will become apparent to those skilled in the art upon examination of the following or may be learned with the practice of the invention.

To achieve the foregoing and other objects, a decreasing pressure grading is applied to the lower limb sequentially from the distal to the proximal portion, thus to prevent the impediment of the blood from returning to the heart. Besides, a pair of lower-abdomen buttock balloons and a chest balloon are added. The control system of the combinated device for external counterpulsation and extrathoracic cardiac masage consists of a single board microcomputer, ADC, DAC, counter and LED. The control system controls sequentially the device of processing inflation and defla tion as well as the monitoring device. Under the control of the microcomputer, , the signal of ECG triggers a mechanical system which exerts pressure over the lower limbs, buttock and lower portion of the abdomen as well as the chest during diastole. In this way a large amount of blood is driven back to the aorta. In connection with the return of the blood, pressure is applied by the extra-thoracic massage instrument so that the amount of blood reaching the brain, the heart, the kidneys and the liver would be considerable, which is quite enough to maintain physiological requirements. This will improve the effect of counterpulsation and resuscitation. While in systole, all the parts exerting pressure are quickly relieved. Owing to the decrease in intravascular pressure , the systolic pressure is lowered, thus the resistance is lowered when the heart contracts, -(After load) and the oxygen consumption of the heart is thus diminished.

In addition , a counterpulsation bed is provided, which is especially suited for the combinated device for external counterpulsation and extrathoracic cardiac massage apparatus for clinical use. The bed is designed in accordance with the physiological curvature of the body with respect to its concave and convex surface. The ends of the bed can be raised and lowered. There are noise muffling hoods over and beneath the bed. The cardiac massage device is placed in a fixed position. Thus the bed is kept off the noise to leave the patient in a comfortable state while giving efficiency to the treatment.

In a further aspect of the invention, in accordance with its objects and purposes , a method is applied through the use of the combinated device for external counterpulsation and extrathoracic cardiac massage on sudden-cardiac-arrest patients and on those patients with organ anoxia while the heart is still pumping.

For the sudden-cardiac-arrest patient, the device by means of computer control, sends out a pulse signal with a frequency of 30 -80 times per minutes. Each pulse signal indicates a pressurized cycle, each of which triggers a mechanical system, which again, when the heart is in diastole, sequentially applies a decreasing pressure grading from the distal to the proximal portions on the balloons wrapped around the legs, the thighs, the liver -abdomen -buttock and the chest . This will force the blood to the body to supply the main organs, as the brain, the heart, the kidneys, the lungs and the liver, etc., and to maintain effective and near-physiological-state blood circulation. While in systole all the balloons deflate simultaneously. Thereafter the balloons over the chest and the lower-abdomen-buttocks are sequentially inflated, to drive blood to the lower parts of the body for the use of the next pressurized cycle.

For those patients recovering from cardiac resuscitation , yet with a lower return blood wave during the diastolic phase of the heart beat, and also for those patients with organ ischemia , the combinated device under the control of the computer will improve their blood supply and promote the establishment of collateral circulation. The computer will first detect QRS wave as a signal to trigger a mechanical system which, during cardiac diastole, will sequentially inflate with pressure grading the balloons wrapped around the legs, the thighs, the liver -abdomen -buttock and the chest. This will drive a large amounts of blood to the aorta and produce another set of " pulse " to perfuse the organs, such as the brain, the coronary arteries, the kidneys, the lungs, etc. The balloons, in the next cycle of the cardiac systole,will deflate rapidly, so as to lower intravascular pressure, to lessen the after load, and to decrease the oxygen consumption of the heart.

A preferred embodiment of this invention is shown an described in the following description, simply by way of illustration of one of the modes best suited to carry out the invention. The several details of the invention are capable of modification in various, obvious aspects all without departing

from the invention. Accordingly, the drawing and description will be regarded as illustrative in nature and not as restrictive.

Figure 1 is a systematic schematic diagram of the present invention of a combinated device for external counterpulsation and extratheracic cardiac massage apparatus with a chest balloon in it.

Figure 2a is a diagram of the structure of liver-abdomen-buttock balloons.

Figure 2b is a diagram of the liver-abdomen-buttock ballons applied to the body of the patient.

Figure 3a is a diagram of the structure of the extrathoracic cardiac massage apparatus made of hard material and equipped with a massage head.

Figure 3b is a diagram of the structure of the extrathoracic cardiac massage apparatus made of soft material and equipped with a massage head.

Figure 3c is a diagram of the structure of the extrathoracic cardiac massage apparatus made of soft material without a massage head.

Figure 4 is a schematic electric circuit diagram for the combinated device.

Figure 5 is a diagram of a special counterpulsation bed.

Figure 6 Is a diagram of the controlled sequence of the pulse used for the cardiac-arrest patient.

Figure 7 is a diagram of the controlled sequence of the pulse used for the patient with organ ischemia.

A preferred embodiment of the present invention will now be illustrated in detail following the accompanying drawings.

Reference is now made to Figure 1 showing the combinated device used for counterpulsating a patient with organic ischemia, signal of R wave of ECG or ear-pulse -wave through ECG amplifier (2) or ear-pulse-wave amplifier (3), passing through the single board computer (1) with a preset program of automatic control time delay, then through a power amplifier (31) to trigger opening sequentially 4 inflation solemoid valves (5a), (5b), (5c), (5d), in the gas distribution box, thus rendering positive pressure gas in gas reservoir (7) connected from gas pump (6), in a fixed time passing respectively through Inflation solenoid valves (5a), (5b), (5c), -(5d) in the gas distribution box, thus rendering positive pressure gas in the gas reservoir (7) connected from gas pump (6), in a fixed time passing respectively through Inflation solenold valves (5a) -(5b) (5c) (5d) and pipes (ga), (gb), (gc), (gd) and thence entering into and inflating sequentially and respectively each set of balloons wrapped around the body of the patient from distal to proximal portions. These sets of balloons are leg balloons -(9a) and upper-limb balloons (9a') thigh balloons (9b), buttock balloons (9c) as well as chest balloon (9d) . Except for the chest balloon (9d), each set of the other 4 sets of balloons is composed of symmetrically placed double balloons on both sides of the limbs and buttocks. The inflated balloons exert pressure on the respective parts of the body, yet with a decreasing pressure grading from distal to proximal parts, so that the blood in the 4 limbs and buttocks is driven back to the chest ,and thence to the trunk and the head. After the completion of inflation, in accordance with the preset program of controlled deflation time in single board-computer by the operator, the time is a suitable one before occurrence of the next R wave in ECG, to trigger simultaneously the opening of 4 deflation solenoid valves (10a) (10b) (10c) (10d) in the gas distribution box (4) , and to render deflation of all balloons that exert pressurs on the body. These balloons are the leg balloons (9a) and the upper-limb balloons(9a') the thigh balloons (9b), the buttock balloons (9c) and the chest balloon (9d) . After the completion of deflation, blood is driven to the lower limbs until the next cardiac cycle, the same sequence of events is repeated. The gas pump (6) though connecting pipes supplies positive pressure gas to gas distribution box (4). The gas pump (6) is a greaseless membrane type of low -pressure, large-flow. The single board computer (1) is connected to the display unit (48) for dsplaying ECG or ear-pulse-wave.

In case the combinated device used in rescueing a patient with cardiac arrest without showing ECG or ear pulse wave, in their stead, the computer, according to the selected preset constant (20) dispatches pulsed signals with a frequency of 30 -80 times per minute, after the completion of the above-mentioned program of inflation -deflation balloons, then the power amplifier (31) triggers the sequential opening of inflation salenoid valves (5d) and (5c) in the gas distribution box (4): the positive pressure gas in the gas reservoir (7)

enters the chest balloon (9d) and the lower-abdomen-buttock balloons (9c)to exert pressure on the respective parts and to drive blood to the lower limbs more effectively. After the completion of the inflation, the deflation valves open simecltaneously, thus gas in chest balloon (9d) and lower-abdomen-buttock is expelled to the atmospher. After the completion of deflation, another pulsed signal appears, and the same program is repeated.

In figure 2a is a pair of lower-abdomen-buttock balloons (9c) symmetrically placed on the right and left sides, inserted into the interleaves of a bag - (11) tailed to profile of the buttock and being able to be wrapped onto it tightly . Each balloon when lying flat has a surface area of more than 300 cm², and an internal pressure 160 -250 mmHg, lower than that in the leg balloons (9a) and the thigh balloos (9b) . As shown in Figure 2b, the bag (11) is wrapped onto and fixed to the buttocks by nylon fasteners.

Figure 3a represents the structure of a hard extratheracic cardiac massage apparatus with a massage head , whose casing is of either a cubic or circular box (14) in which the chest balloon (9d) with its channel (13) is located . At the center of the top and bottom of the box, there is a hole (19) ~ (19') . The balloon channel (13) passes through the top hole (19) to connect the pipes (8D) coming from the inflation -deflation solenoid valves (5d) and (10d). Located closely underneath the chest balloon (9d) is a push board (15) , the center of the board bottoom is fixed to a rod (42) which passes through the hole (19') in the bothom of the box with a spring (17) attached. The other end of the rod is fixed to a massage head. A regulating screw (18) is inserted between the push board - (15) and the casing . In static condition, both the push board (15) and the massage head (16) are pushed upward by the spring (17), so as to empty the chest balloon (9d). During inflation -distention of the chest balloon (9d), the push board (15) moves downward by pressure , and thus the massage head (16) moves dounward too, to press tightly onto the lower end of the sternum. The moving distance between the two is 2,5 to 5 cm. The pressure exerted is 35 to 50 Kg. By adjusting the regulating screw, the moving distance as well as the pressure can be controlled. During deflation of the chest balloon (9d) both the push board (15) and the massage head (16) return to their original position by means of the spring (17). The chest ballon - (9d),when lying flat, has a surface area of 100 to 150cm on one side, and the pressure after inflation is 0.35 to 0.50 kg/cm.

Figure 3b and 3c either is a structure diagram of a soft massage apparatus which can be wrapped and fixed around the chest. That wrapped around the chest is a ring-shaped bag (14), made of leather, leatheret or woven fabric and being able to be fastened together by a nylon fastener. Inserted in the bag (14) Is a chest balloon (9d) while the channel (13) of the balloon passes through a hole - (19") in the bag and is connected with the pipes - (8d) coming from the inflation-deflation solenoid valves (5d) and (10d) which are connected to the chest balloon too. In Figure 3b , underneath the chest balloon (9d) is a push board (15'), the bottom of which is connected to a cardiac massage head (16'). Both of them are wrapped together in the bag (14') . When in use, the massage head (16') is placed to the lower part of the sternum. While in Figure 3c, only the chest balloon (9d) is in the bag (14') without the push board and massage head. When in use, the chest balloon (9d) as well as the bag (14') is tightly applied to the lower part of the sternum.

Reference is now made to the schematic diagram of the systematic electric circuit of the combinated device as shown in Figure 4 . During counterpulsation, the ECG wave through its amplifier (2) , ear-pulse-wave through its amplifier (3) or a preset constant (20) entering into the main electric circuit, pass through ADC (21) to be digital signals sent into CPU (22). The ECG amplifier(2) is composed of a two-level amplifier with amplification factor of 500, 1000 and 2000, to yield voltage -level signal to ADC (21), CPU (22) , EPROM (23), RAM - (24), CTC (25), LED (26), counter (27), PIO (28), DAC (34), (34') in the main electric circuit, and through A/D transformation , to filter and detect QRS wave gronps, making a timed computerization and display. In order to insure that the electric circuit has a common mode rejection ratio above 90 dB, it makes use of a preamplifier comprising three computing amplifiers, one of which is a main amplifier, while the other two are followers. Ear-pulse wave amplifier (3) is a two-level amplifier comprising two computing amplifiers, with an amplification factor of 500,1000 and 2000,and amplifying the signals received by light sensitive diode to voltage level,which (the signal) through processing by the main electric circuit is ready for display. ECG amplifier (2) and ear -pulse -wave amplifier, each of which has an emitter follower to match the main electric circuit, limiting the ontput signal to below 5 volts, thus protecting ADC (21).

CP (22) is timed by CTC (25),under the control of the storage instruction in EPROM (23), through digital filtering of ECG or ear -pulse wave, to input digital signals into RAM (23) , and detect QRS wave groups from ECG or ear -pulse wave. According to the following formulae, timing constants may be obtained:

$$T_1 = \begin{cases} 1/4 \quad T_r - C_1' + C_1 & (300ms \leqslant T < 850ms) \quad (1) \\ 1/5.2 \ Tr - C_1'' + C_1 & (850ms \leqslant T < 1250ms) \quad (2) \end{cases}$$

$T_2 = Tr - T_1 - C_2$

Where, T_1 -time of beginning of inflation derived from CPC (22)

T_2 -time of beginning of deflation

Tr -R -R period of ECG

C_1' , C_1'' -in set constant of inflation

C_1 -out set constant of inflation

C_2 -out set constant of deflation

Inflation time T_1 is the time interval between R wave to the time of the beginning of inflation. Deflation time T_2 is the time interval between T_1 and the time of the beginning of deflation. C_1 and C_2 in the formnlae are formed by preset constant in subroutine, and C_1 is related to factors as the time - delay control (due to electric or mechanical factors and the patient's individual variation). To keep the inflation time at an optimum the system can automatically follow the variations of the pulse rate and thus adjust the time when to begin the inflation .

It needs only to adjust C_1 to augment the diastolic pressure to a suitable level. C_2 is the time interval between the time of deflation and the next R wave.

The above formula (1) is derived and simplified from the empirical formula $T_1 = 0.4 \sqrt{Tr} + C_1$ (tracing error less than 10 ms).

In order to trace the R -R period (Tr) variation accurately and to diminish the influence of random factors, first the average value $\overline{Tr}$ of Tr is obtained by adding two Tr and dividing by 2 ; then take next normal Tr (those deviationfrom mean is less than 120 ms), and according to the formula - ($\overline{Tr}$ + Tr) /2, rectify $\overline{Tr}$ of the last time.

After deriving the time (T_1) of the beginning of inflation and the time (T_2) of the beginning of deflation, from A port of PIO (28) it delivers a control signal of the beginning of inflation and deflation to the inflation -deflation processing device to drive solenoid -valve sets (32), and thus to control inflation and deflation of the balloons. The sequential processing device consists of a sequential control circuit (30), of which the 8D trigger is the main component, and a power amplifier (31) at each level of the electric circuit. The pulse rate and the time of the beginning of inflation and deflation, as computed by CPU (22), are sent to two sets of LED (26) of 3 digits for displaying. CPU (22) controls counter (27) and through DAC (34) produces X-axis-scan serrated wave, which is then sent to an X-axis deflection system (35) of the monitor. CPU - (22) fetches the signal from RAM (24) and through B port of PIO (28), the signal is sent to another DAC (34) forming the Y-axis deflection (36) system of the monitor. Under the action of the function switch, the signal can be displayed dynamically or statically or the speed of scanning can be varied. The timing alarm signal for one hour conterpulsation is sent to timed alarm (36) by CPU (22), to give visual and audible alarm.

CPU (22) sends blank signals while PIO (28) sends synchronous signals to the monitoring device (39). The monitoring device consists of the power amplifying circuit of the X, Y deflation system (35) (36), synchronous and blanking signal amplifying circuit (40) (41), high voltage circuit and CRT (not shown). Under the control of the main circuit, the monitor displays synchronously double-track 3 signals (ECG signal, inflation-deflation signal, ear-pulse-wave signal) or double track 2 signals (ECG signals and inflation -deflation signals), and possesses the ability of locking images.

The main functions of the electric circuit of the combinated device, such as ECG digital filteration, QRS wave-gronp detection, pulse rate calculation, inflation-deflation timing calculation, protection of automatic deflation, functioning of double track signals and image locking and time -based scanning serrated wave are all performed by software.

Once power is on, the system goes to zero suppression automatically, and executes an initial program, sets A-port of PIO in the position of control and B-port in the state of output. 2000-203F in 2K ROM is the data area of the system. which stores time variable parameters of the system, such as pulse rate and the time of beginning of inflation and deflation. 2047-27FF stores digital signals of two channels. After initialization of the computer, through A/D of ADC, the digital signals of ECG undergo a two-point-smoothing process, thence through digital fitteration, 50 HZ disturb signals are taken off. Then through QRS wave group discrimination program, detect QRS wave group; through pulse-rate subroutine calculate pulse rate, and through inflation-deflation subroutine compute inflation-deflation timing interval. When the interruption of timed 10ms, as produced by CTC, happens, execute the digital display subroutine.

When interpointer of signal display adds 1, the data in the storage area alternate incessantly. Read the data in channel 1 (CH_1) first, thereafter read the data in channel 2 (CH_2), and read out alternatively the two interleaved channels. Due to incessant change of the data in the storage area, dynamic signals are displayed on the screen, with each displaying for 10ms of which 5ms for read out the data, and 5ms for changing the data. When the image is being locked, new data stop to enter the storage area. Then the original data is repeatedly read out in the storage area for resident displaying.

In the soft-ware of the system, the suitable time for the beginning of inflation T_1 ranges from 10 to 850ms, while the time for the beginning of deflation T_2 ranges from 5 to 800ms. The range can be increased by a revision of the software.

Although a patient may lie on an ordinary bed for treatment, yet it is far better to utilize a special counterpulsation bed in question for the patient in using this combinated device. The special counterpulsation bed, as shown in Figure 5, is designed in accordance with the physilolgical curvature of the human body with respect to its concave and convex surfaces. The end of the bed can be raised or lowered down, and a noise muffler (43) is placed underneath the bed, the gas distribution box (4) being under its cover. Another noise muffler (43') which can rotate by 220° and be detached if not desired, is placed at the end of the bed. Holes -(44) are made in the bed for passage of pipes that connect inflation solenoid valves to their respective balloons. When the bed is used for a patient with cardiac arrest, it is better to place a specially-made supporting board (45) on the bed, for a patient to lie on back. Four tapes (46) are attached to four corners of the supporting board for use to secure the hard cardiac massage apparatus to a suitable position, so that the massage head can be accurately placed over the lower end of the sternum as shown in Figure 2A. It is also possible to use soft massage apparatus with a massage head as shown in Figure 2b, or to use a soft massage aparatus without massage head, yet with poor results. For use on a counterpulsating patient, the supporting board (45) on the counterpulsation bed may be taken away, while the soft massage apparatus without massage head as shown in Figure 3c should be used.

Figure 6 represents the controlled-pulse time sequence of the combinated device of the present invention used for a patient with cardiac arrest. Under the control of the microcomputer, pulsed signals are generated with a frequency of 30-80 times per minte to control sequentially the inflation and deflation of the balloons, through trigger 8D to deliver control pulse in sequence, and through power amplification to drive respective solenoid valves, thence the balloons in strict accordance with the set sequence and time, undergo inflation and deflation.

In Figure 6, the square waves above the base line represent the pulses for inflation, while those below the base line repressent the pulses for deflation. The width of the square wave represents the time interval for opening either inflation solenoid valves or deflation solenoid valves, and each blank in abscissa represents 40ms. Square wave (51) respresents opening of solenoid valve (5a) which renders inflation of leg balloon (9a) and upper-limb balloons (9a'). Square wave (52) represents opening of solenoid valve (5b) which renders inflation of the thigh balloons, square wave (53) represents opening of solenoid valve (5c) which renders in flation of the lower-abdomen-buttock balloons (9c). Square wave(54) represents opening of solenoid valve (5d) which renders inflation of the chest balloon(9d). Square wave(55) represents simultaneous opening of 4 sets of deflating solenoid valves 10a, 10b, 10c, 10d which render simultaneous deflation of 5 sets of balloons. The time interval of square waves (54) and (55) can be adjusted in the range of 50 to 150ms. Square wave (56) represents reopening of solenoid valve (5d) which causes inflation of the chest balloon (9d)

inserted in the massage apparatus. Square wave - (57) represents reopening of the solenoid valve which renders inflation of lower-abdomen-buttock balloon. Square wave (58) represents simultaneous deflation of the chest balloon (9d) and the lower-abdomen-buttock balloon. In this way, the process of massage cycle is completed. The cycle may be repeated or varied according to the change of the time interval between square waves (55) and (56) as well as between square wave (58) and the first square wave (51') in the next cycle. Its range is 30 to 80 times per minute. The number of repetitions can be set according to need.

Figure 7 represents the controlled-pulse sequence of the combinated device of the present invention used for patients with heart beat. The device detects patient's ECG, under the control of the microcomputer through trigger 8D, the QRS wave trigger controlled pulse in sequence as shown in Figure 7, through power amplification to drive respective solenoid valves rendering inflation and deflation of the balloons in strict accordance with the set sequence and the time. A comparison between Figure 7 and Figure 6 shows that the massage cycle includes only the sequential inflation and simultaneous deflation of the leg balloons - (9a) and the upper-limb balloons (9a'), the thigh balloons (9b), the lowe-abdomen-buttock balloons - (9c) and the chest balloon (9d).

When the above-mentioned combinated device is used in counterpulsating a patient with ischemic organ, the pipes (8a) will connect the first set of inflation solenoid valve (5a) and deflation solenoid valve (10a) to the leg balloons (9a) and upper-limb balloons (9a'). As an alternative, the upper-limb-balloons(9a')can be taken away while not in use, the inflation (5a) and deflation solenoid valves - (10a) connected solely to the leg balloons,or the chest balloon (9d) may be taken away, or the chest balloon (9d) and the upper-limb-balloons can be taken away together. Yet the use of the chest balloon (9d) will give the better result.

The clinical and experimental data have shown that when performing counterpulsation and extratheracic cardiac massage, the time interval for sequential ininflation of each set of balloons is best set at 40 to 120 ms, the time duration for inflating balloons is 75 to 120 ms. The positive pressure gas from the gas reservoir in passing through the solenoid valves and entering into the balloons for inflation results in a variation in pressure, since the size of each set of balloons is different while the time of inflation is the same. The pressure in the leg balloon (9a) and the upper-limb balloons (9a') is approximately 250 to 300mmHg, that pre-ssure in the thigh balloons (9b) is approximately 220 to 270mmHg, and that pressure in the lower-abdomen-buttock balloons is approximately 200 to 250mmHg. The deflation time lasts for 100-120ms.

The adoption of the above-mentioned method of sequential inflation and dereasing pressure grading will drive a sufficient amount of blood in the lower part of the body back to the trunk, thus diastolic pressure will be augmented conspicuously, to render most patients D/S (ear-pulse-wave deastolic amplitude / systolic amplitude)>1.2, and even to reach 2 to 4 for some of them. In a patient with sudden cardiac arrest, when the blood is returning to the arch of aorta, an inflation pressure of 0.35 to 0.5Kg/cm² is required to inflate the chest balloon (9d) of the extratharacic cardiac massage apparatus to cause a downward movement of 2.5 to 5cm of the massage head (16), and to exert a pressure of 35 to 50Kg over the lower portion of the sternum, in order to produce a "heart stroke" with a stroke volume of 40-100cc.

When the combinated device of the present invention is used as external counterpulsation for clinical treatment of patients with coronary heart disease nad angine pectoris, the symptoms after external couterpulsation have been relieved in most patients with a rate of effectiveness of 90.3%: further more conspicuous effects have been seen in patients with ischemic diseases of the brain, the retina, the kidney and the peripheral vessels. The results will be much better, if at the time of external counterpulsation, an intravenous dripping of thrombolytic drugs is used. The chance of resuscitating a patient with sudden cardiac arrest is greater in using this combinated device than ordinary extrathoracic cardiac massage apparatus.

Obviously, many modifications and variations of the present invention are possible in the light of the above teaching.

Claims

1. A combinated device for a computerized enhanced model of external counterpulsation and extrathoracic cardiac massage apparatus, comprising: an ECG amplifier (2), an ear-pulse -wave amplifier - (3), a monitoring device, a timing control device for sequential inflation and deflation, a counterpulsation bed, leg balloons, thigh balloons, gas pump, gas reservoir, extrathoracic cardiac massage apparatus, two sets of inflation solenoid valves and a deflation valve mounted in a gas distribution box connected respectively to the leg balloons, the upper-limb balloons and the thigh balloons through piping,characterized in that the means comprises also

a pair of lower abdomen-buttock balloons and a chest balloon placed inside the extrathoracic cardiac massage apparatus, in addition to another two sets of inflation-deflation solenoid valve in the gas distribution box connected respectively to lower abdominal buttock balloons and chest balloon through piping.

2. The device according to Claim 1, wherein said control device includes a timing device and sequential processing device, in which, the said timing device includes an A/D-C to convert the ECG, ear -pulse -wave and preset constants into a digital signal; a CTC for timing inflation and deflation; an EPROM to store compiled programs; a CPU to filter the digital signal of ECG and ear -pulse-wave, wich under the instruction control of EPROM and according to the formulae below:

$$T_1 = \begin{cases} 1/4\ Tr - C_1' + C_1 & (300ms \leqslant T \leqslant 850ms) \\ 1/5.2\ Tr - C_1'' + C_1 & (850ms < T \leqslant 1250ms) \end{cases}$$

$$T_2 = Tr - T_1 - C_2$$

calculates the time initiating inflation and deflation and compiling control program; a RAM to store a digital signal and the contr0l program calculated by CPU; the A-port of a PIO receiving initiating time of inflation and deflation from CPU and sending a control signal to initiate inflation and deflation to a sequential processing device; the B-port of the PIO sending a signal from RAM through CPU to DAC; a LED to display pulse rate and time to initiate deflation by CPU , said sequential processing device incorporating a cir cuitry and a power amplifier.

3. The device according to Claim 1 or 2, wherein said monitoring device includes a counter controlled by CPU ; a DAC connected to the counter to produce an X -axis scan serrated wave; another DAC to convert the output of B port of PIO into an Y-axis,analogue signal, the monitoring device further including a monitor which consists of an X,Y-power amplifier comprising an X-axis deflection system to receive an X-axis scan serrated wave and an Y-axis deflection system to receive an Y-axis analogue signalå amplified electric circuit to receive a blanking signal inputted from CPU ; an amplified synchronous signal electric circuit to receive a synchronous signal inputted from PIO; high voltage electric circuit and a CRT.

4. The device according to Claim 1 wherein said lower-abdomen-buttock balloons are paired and fixed inside a jacket relative to tailored to the profile of the left and right buttocks, and can be wrapped tightly onto there.

5. The device according to Claim 4 , wherein the lower-abdomen-buttock balloon has a surface area not less than 300 cm on one side when lying flat.

6. The device according to Claim 4 , wherein said lower-abdomen -buttock balloons require a pressure of 160 -250 mm Hg , less than that in leg and thigh balloons.

7. The device according to Claim 1, wherein said extrathoracic cardiac massage apparatus is made of hard material and has a chest balloon inserted into the interleaves of a box-shaped casing, a hole being drilled in the center of the bottom and top of the casing, with a rod passing through the bottom hole at one end and fixed to a push board tightly, placed underneath the bottom of the balloon, while the other end of the rod being fixed to a massage head.

8. The device according to Claim 7 , wherein said extrathoracic cardiac massage apparatus with the inset of the chest balloon has a spring placed in that end of the rod connected to the push board and regulating screw being laced between the casing and the push board.

9. The device according to Claim 1, wherein said extrathoracic cardiac massage apparatus housing the chest balloon has its casing made of soft material and is formed like a finger-ring-shaped bag on which a hole is made as the opening to the chest ballon.

10. The device according to Claim 9, wherein said extrathoracie cardiac massage apparatus housing the chest balloon further includes a push board tightly placed underneath and a massage head fixed to the center of the push board bottom, both being wrapped within the bag.

11. The device according to Claim 1, 7, 8, 9 or 10,

wherein said chest balloon when lying flat has a surface area of 100 to 300 cm on one side.

12. The device according to Claim 11, wherein said chest balloon when inflated has an internal pressure of 0.35-0.50 kg/cm².

13. The device according to Claim 1, wherein said counterpulsation bed is one specially made for counterpulsation and is designed in accordance with the normal physiological curvature of the body with respect to its concave and convex surfaces wherein the head of the bed can be raised and lowered, a detachable supporting board is placed on the bed relative to the position of the back of a patient when lying down, and to each of the four corners of the board a tape is attached to fasten the hard massage apparatus which is to be placed right to the position of the lower end of patient's sternum.

14. The device according to Claim 13, wherein said counterpulsation bed has holes for the passage of pipes that connect inflation-deflation solenoid valves to their respective balloons.

15. The device according to Claim 13 or 14, wherein said special counterpulsation bed is equipped with a noise muffling hood.

16. A method for application of a device of claims 1 to 15 for external counterpulsation and extrathoracic cardiac massage apparatus for patients with sudden cardiac arrest, the steps of using the device comprising: :

counecting 4 sets of inflation-deflation solenoid valves respectively with leg balloons, thigh balloons, lower abdomen-buttock balloons as well as chest bal loon;

dispatching a pulsed signal with a frequency of 30 to 80 times/min. to control sequentially for inflation and deflation of the balloons, under action of said controlling device, opening in turn the 4 inflation solenoid valves during the diastole, so as to inflate sequentially the leg balloons, the thigh balloons, the lower-abdomen -buttock balloons as well as the chest balloon which is connected with said 4 inflation solenoid valves respectively;

deflating each set of balloons simultaneously through opening of the 4 deflation solenoid valves during systole;

opening two inflation solenoid valves connected respectively with the chest balloon and the lower-abdomen-buttock ballons, so as to inflate sequentially these two sets of balloons; opening two deflation solenoid valves which are connected respectively with chest balloon and lower-abdomen-buttock balloons, so as to deflate these two sets of balloons;

in accordance with the preset pulsed signal repeating the above steps.

17. A method of application of a device of claims 1 to 15 for an external counterpulsation and extrathoracic cardiac massage apparatus for patients with heart beat of organ ischemia, the steps of using the device comprising:

connecting 4 sets of inflation -deflation solenoid valves respectively with the leg balloons, the thigh balloons, the lower-abdomen -buttock ballons as well as the chest balloon of a patient;

detecting patient's ECG, with its QRS wave triggering under the action of said control device, opening in turn the 4 inflation solenoid valves during the diastole, so as to inflate sequentially the leg balloons, the thigh balloons, the lower-abdomen -buttock balloons as well as the chest balloon which connected with said 4 inflation solenoid valves respectvely ;

opening the 4 deflation solenoid valves during the systole so as to deflate each set of balloons simultaneously ;

repeating the above steps as required .

18. A method of application of a device of claims 1 to 15 for external counterpulsation and extrathoracic car diac massage apparatus for patients with heart beat of organ ischemia, the steps of using the device comprising:

connecting 3 sets of inflation -deflation solenoid valves respectively with the leg balloons , the thigh balloons and the lower-abdomen-buttock balloons;

detecting patient's ECG, its QRS wave triggering under the action of said control device, opening in turn said 3 inflation solenoid valves during the diastole, so as to inflate sequentially the leg balloons , the thigh balloons and the lower-abdomen - buttock balloons which are connected with said 3 inflation solenoid valves respectively;

opening simultaneously said 3 deflation solenoid-

valves during the systole, so as to deflate simultaneously the above -mentioned each set of balloons; repeating the above steps as required.

19. The method of application of said device according to claim 16, 17, or 18, wherein said leg balloons are connected with said inflation -deflation solenoid valves together with the upper -limb balloons.

20. The method of application of said device according to Claims 16, 17, 18 or 19, wherein said inflating time of said each set of balloons lasts for 75 to 120 ms , the time interval of inflation is 40 to 120 ms , the time of deflation lasts for 100 to 120 ms.

21. The method of application of said device according to Claim 16, wherein said counterpulsation bed has a support board placed on it , said extrathoracic cardiac massage apparatus has a massage head made of hard or soft material.

0 203 310

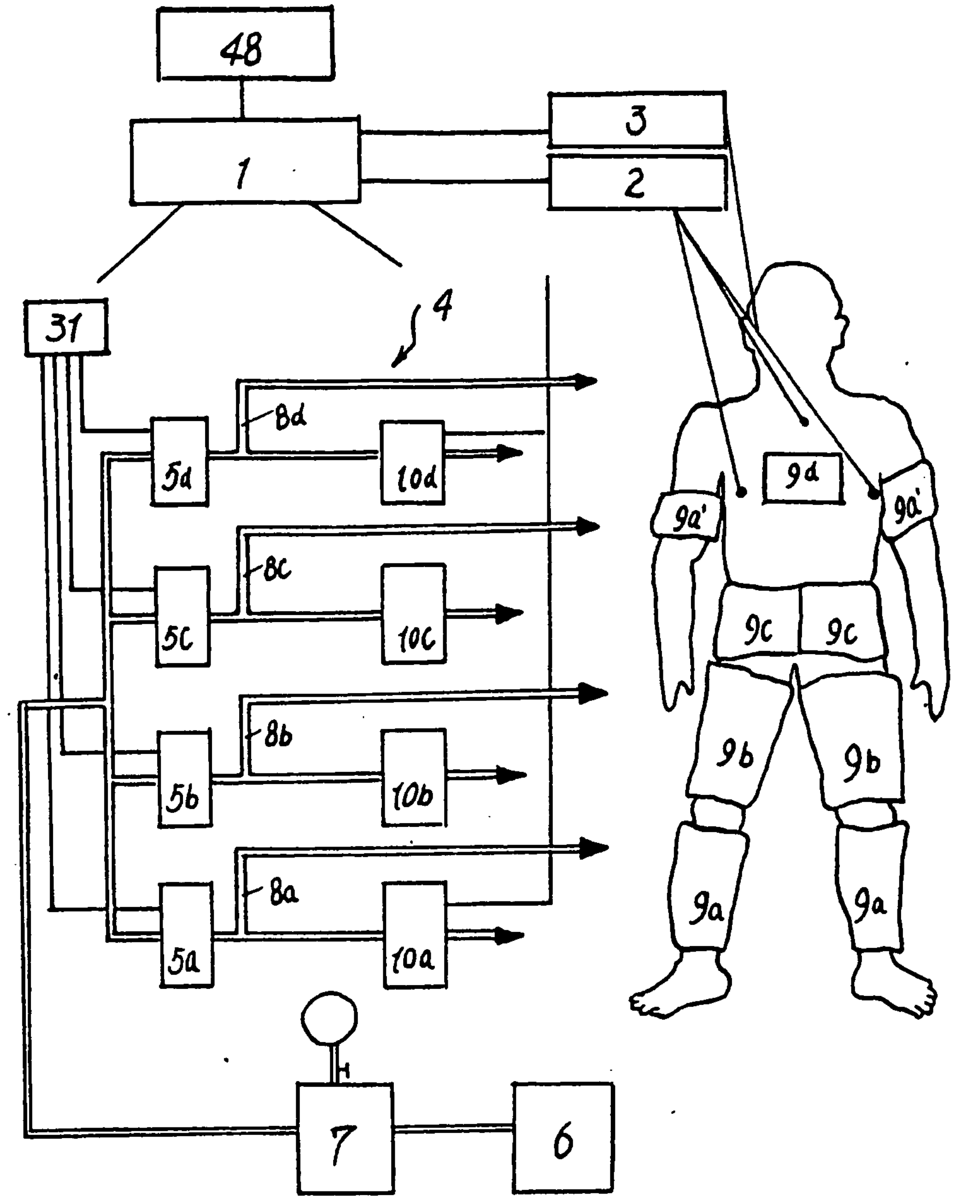


Fig 1

0 203 310

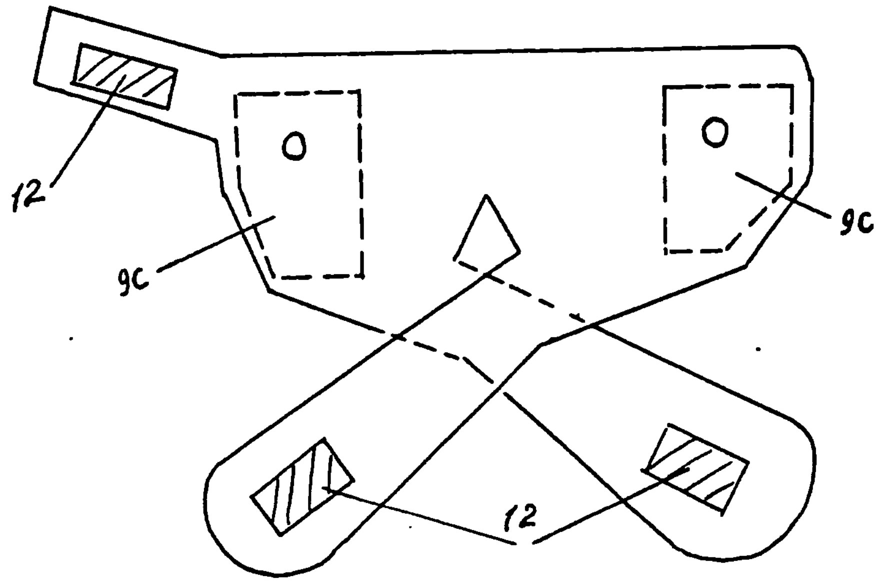


Fig 2a

Fig 2b

0 203 310

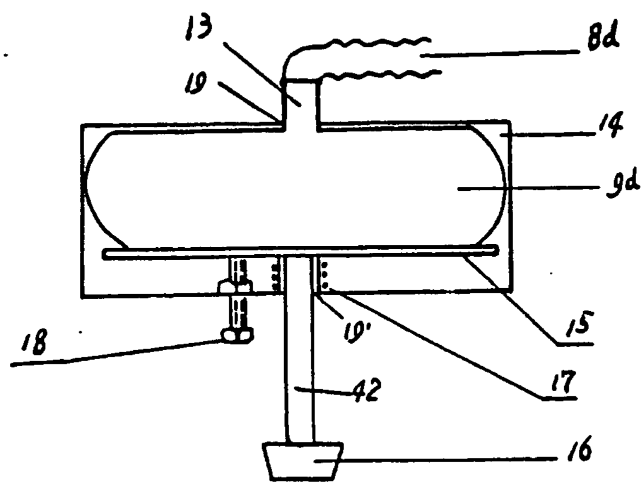


Fig 3a

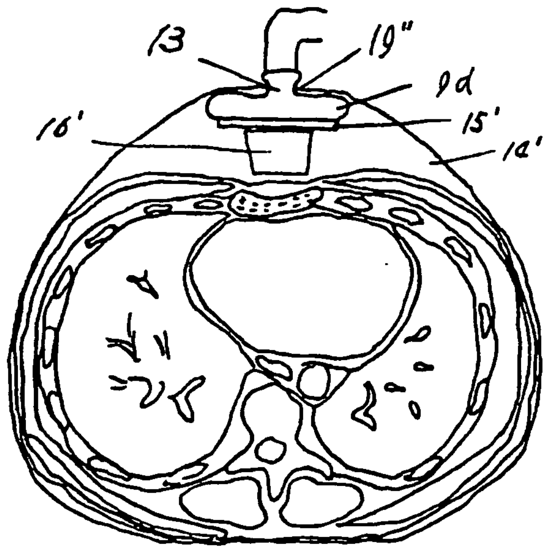


Fig 3b

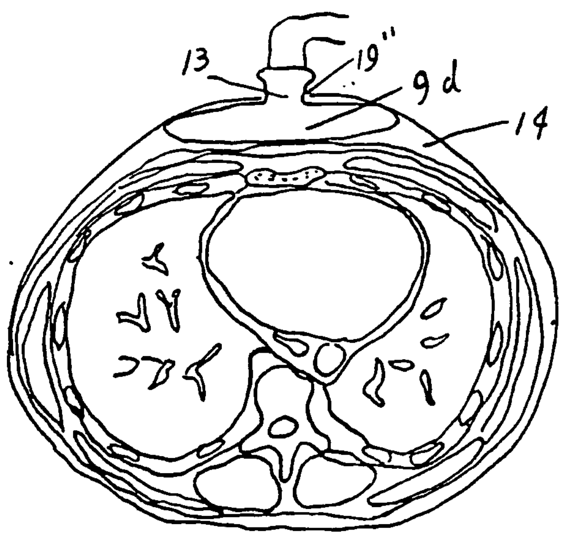


Fig 3c

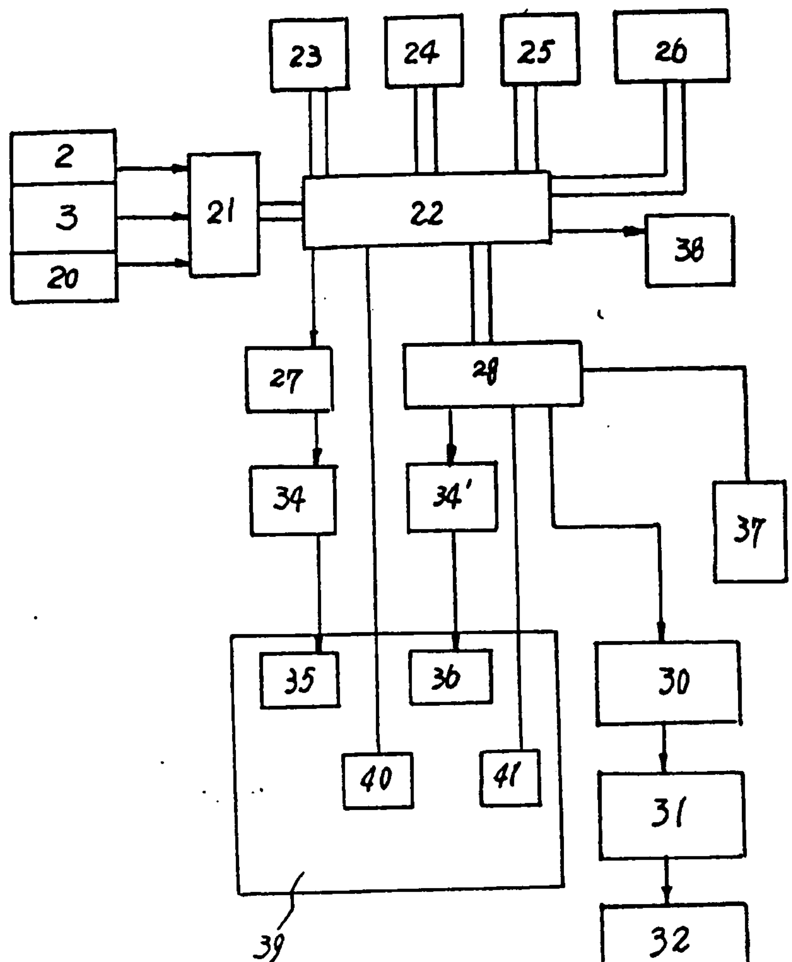


Fig 4

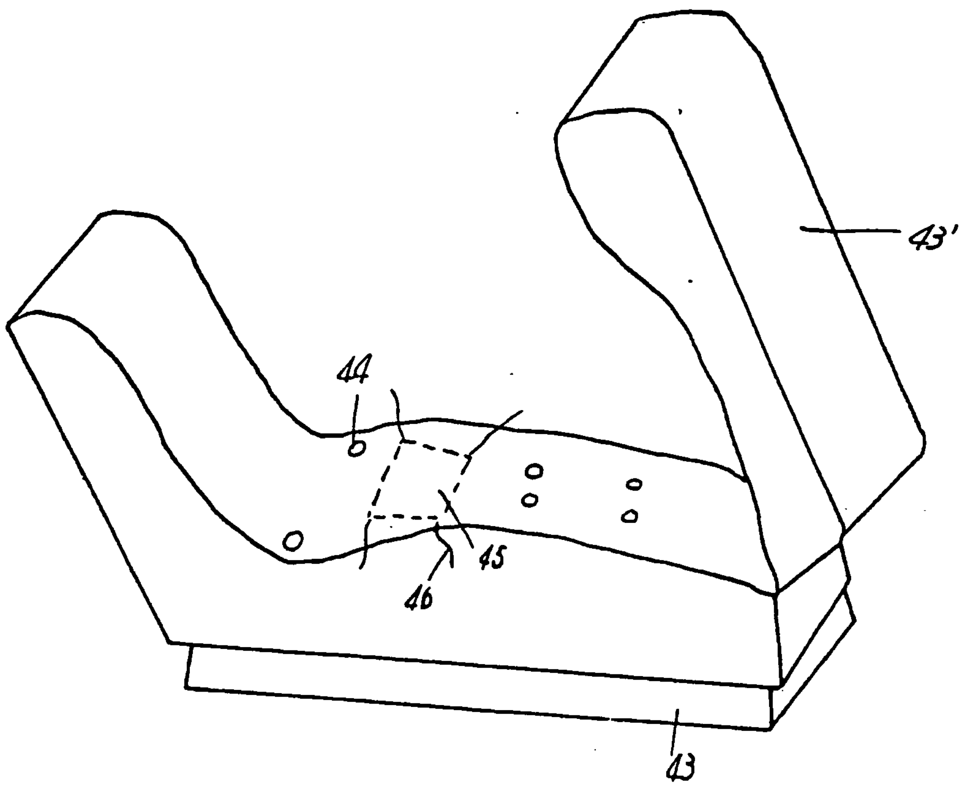


Fig 5

0 203 310

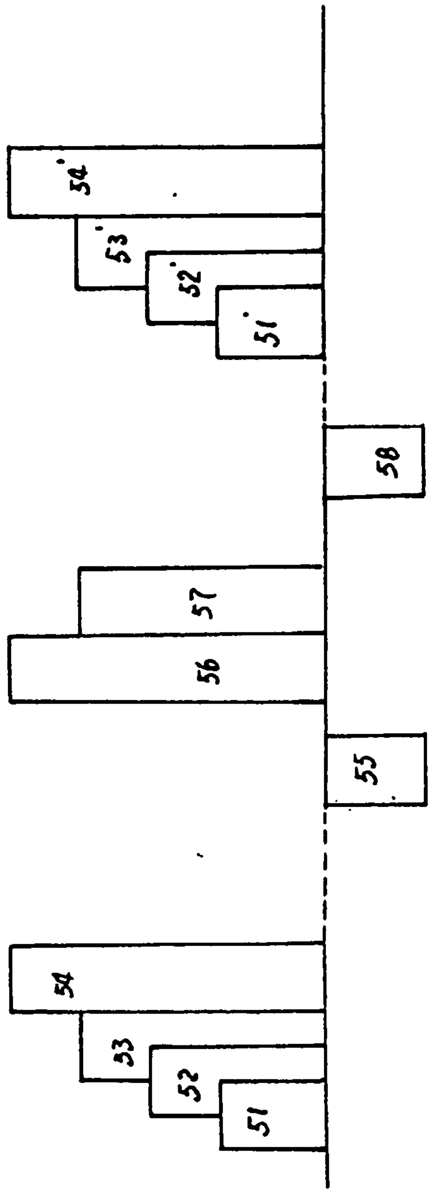


Fig 6

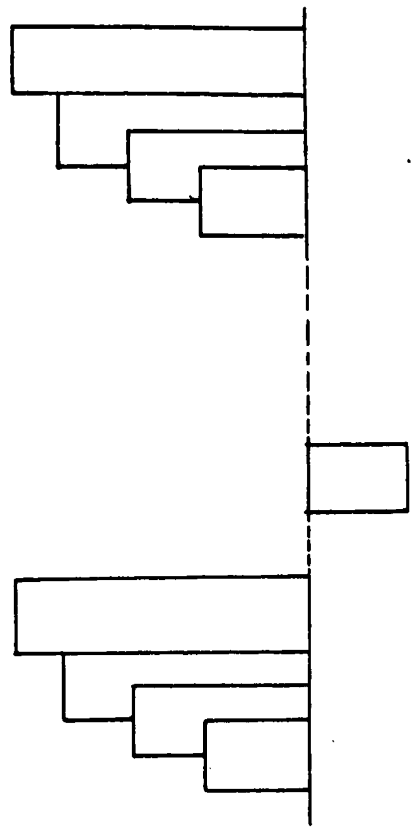


Fig 7